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Doran R. Pace, Patent Attorney

INFORMATION DISCLOSURE  
STATEMENT

Examining Group 1632

Patent Application

Docket No. CNG-100D1

Serial No. 09/826,025

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1632  
Applicant : Lung-Ji Chang  
Serial No. : 09/826,025  
Filed : April 4, 2001  
For : Combination Immunogene Therapy

Assistant Commissioner for Patents  
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.97 and §1.98, Applicant would like to bring to the attention  
of the Examiner, the references cited in the following patent application:

U.S. Serial No. 08/838,702, filed April 9, 1997.

The subject application, Serial No. 09/826,025, claims the benefit under 35 USC §120 of the filing  
date of patent application Serial No. 08/838,702. Applicant respectfully requests that the copies of  
references supplied in the Information Disclosure Statements of the 08/838,702 application, as well  
as references cited during prosecution thereof, be made of record in the 09/826,025 application. As  
copies of the references filed in the 08/838,702 application, and cited on the attached form PTO-  
1449, can be found in the 08/838,702 casefile, copies of those references are not provided herewith.

It is respectfully requested that the references cited in the 08/838,702 application be  
considered in the examination of the subject application and that their consideration be made of  
record.

Applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



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DRP/sl

Attachment: Form PTO-1449

Form PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
CNG-100D1SERIAL NO.  
09/826,025INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

APPLICANT(S): Lung-Ji Chang

FILING DATE  
April 4, 2001GROUP  
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## U.S. PATENT DOCUMENTS

| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | NAME                   | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|----|-----------------|---|---|---|---|---|---|----------|------------------------|-------|----------|-------------------------------|
|                      | AA | 5               | 6 | 8 | 1 | 5 | 6 | 2 | 10/28/97 | Sobol <i>et al.</i>    |       |          |                               |
|                      | AB | 5               | 7 | 3 | 8 | 8 | 5 | 2 | 4/14/98  | Robinson <i>et al.</i> |       |          |                               |
|                      | AC | 5               | 6 | 3 | 7 | 4 | 8 | 3 | 6/10/97  | Dranoff <i>et al.</i>  |       |          |                               |
|                      | AD | 5               | 9 | 8 | 6 | 1 | 7 | 0 | 11/16/99 | Subeck                 |       |          |                               |
|                      | AE |                 |   |   |   |   |   |   |          |                        |       |          |                               |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|----|-----------------|---|---|---|---|---|---|----------|---------|-------|----------|-------------|----|
|  |    |                 |   |   |   |   |   |   |          |         |       |          | YES         | NO |
|  | AF | 9               | 3 | 1 | 0 | 2 | 1 | 9 | 11/13/92 | WO      |       |          |             |    |
|  | AG | 9               | 7 | 3 | 2 | 9 | 8 | 7 | 3/2/97   | WO      |       |          |             |    |
|  | AH | 9               | 6 | 1 | 1 | 2 | 7 | 9 | 10/2/95  | WO      |       |          |             |    |
|  | AI | 9               | 6 | 4 | 0 | 2 | 3 | 8 | 6/5/96   | WO      |       |          |             |    |
|  | AJ |                 |   |   |   |   |   |   |          |         |       |          |             |    |

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |  |
|--|----|--|
|  | AK | Agatsuma, T. <i>et al.</i> (1996) "Protection of hu-PBL-SCID/Beige Mice From HIV-1 Infection by a Modified Oligonucleotide, RKS-1443" <i>Antiviral Research</i> 30(1):A35, XP002073900 (abstract 58).  |
|  | AL | Zhang, C. <i>et al.</i> (1996) "Protective Immunity to HIV-1 in SCID/Beige Mice Reconstituted with Peripheral Blood Lymphocytes of Exposed but Uninfected Individuals" <i>Proc. Natl. Acad. Sci. USA</i> 93:14720-14725.                                   |
|  | AM | Lubin, I. <i>et al.</i> (1991) "Engraftment and Development of Human T and B Cells in Mice After Bone Marrow Transplantation" <i>Science</i> 252(5004):427-431.  |
|  | AN | Kilchherr, E. <i>et al.</i> (1993) "Regulation of Human IgE Inhu-PBL-SCID Mice" <i>Cellular Immunology</i> 151:241-256.  |
|  | AO | Mosier, D. <i>et al.</i> (1988) "Transfer of a Functional Human Immune System to Mice with Severe Combined Immunodeficiency" <i>Nature</i> 335:256-259.  |
|  | AP | Mosier, D. <i>et al.</i> (1992) "CD4 T Cells in HIV-1 Infected HU-PBL-SCID Mice" <i>International Congress of Immunology Abstracts</i> , August 23-28, Budapest, Hungary, **abstract only.   |
|  | AQ | Duchosal, M.A. <i>et al.</i> (1992) "Immunization of hu-PBL-SCID Mice and the Rescue of Human Monoclonal Fab Fragments Through Combinatorial Libraries" <i>Nature</i> 355:258-262.   |
|  | AR | Huppes, W. <i>et al.</i> (1992) "Human to Mouse GVHD: A Model for HIV Studies" <i>International Congress of Immunology Abstracts</i> , August 23-28, Budapest, Hungary.  |
|  | AS | Segall, H. <i>et al.</i> (1996) "Generation to Primary Antigen-Specific Human Cytotoxic T Lymphocytes in Human/Mouse Radiation Chimera" <i>Blood</i> 88(2):721-730.  |
|  | AT | Greenwood, J.D. (1993) "Xenogenic PBL-SCID Mice: Their Potential and Current Limitations" <i>Laboratory Animal Science</i> 43(2):151-155.  |
|  | AU | Cayeux, S. <i>et al.</i> (1996) "Coexpression of Interleukin-4 and B7.1 in Murine Tumor Cells Leads to Improved Tumor Rejection and Vaccine Effect Compared to Single Gene Transfectants and a Classical Adjuvant" <i>Human Gene Therapy</i> 7(4):525-529. |

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

|  |    |  |      |                               |                 |                          |                               |
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| Form PTO-1449<br>(REV. 7-80)   |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE   |      | ATTY. DOCKET NO.<br>CNG-100D1 |                 | SERIAL NO.<br>09/826,025 |                               |
| <b>INFORMATION DISCLOSURE STATEMENT</b><br><i>(Use several sheets if necessary)</i>  |    |  |      | APPLICANT(S): Lung-Ji Chang   |                 |                          |                               |
|  |    |  |      | FILING DATE<br>April 4, 2001  |                 | GROUP<br>1632            |                               |
| <b>U.S. PATENT DOCUMENTS</b>   |    |  |      |                               |                 |                          |                               |
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|  | AA |  |      |                               |                 |                          |                               |
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|  | AG |  |      |                               |                 |                          |                               |
| <b>FOREIGN PATENT DOCUMENTS</b>  |    |  |      |                               |                 |                          |                               |
|  |    | DOCUMENT NUMBER  | DATE | COUNTRY                       | CLASS           | SUBCLASS                 | TRANSLATION<br>YES NO         |
|  | AH |  |      |                               |                 |                          |                               |
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|  | AJ |  |      |                               |                 |                          |                               |
|  | AK |  |      |                               |                 |                          |                               |
|  | AL |  |      |                               |                 |                          |                               |
| <b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>   |    |  |      |                               |                 |                          |                               |
|  | AM | Hodge, J.W. <i>et al.</i> (1994) "Induction of Antitumor Immunity by Recombinant Vaccinia Viruses Expressing B7-1 or B7-2 Costimulatory Molecules" <i>Cancer Research</i> 54(1):5552-5555.   |      |                               |                 |                          |                               |
|  | AN | Bueler, H. <i>et al.</i> (1996) "Induction of Antigen-Specific Tumor Immunity by Genetic and Cellular Vaccines Against MAGE: Enhanced Tumor Protection by Coexpression of Granulocyte-Macrophage Colony-Stimulating Factor and B7-1" <i>Molecular Medicine</i> 2(5):545-555. |      |                               |                 |                          |                               |
|  | AO | Liu, Y. <i>et al.</i> (1992) "Costimulation of T-Cell Growth" <i>Current Opinion in Immunology</i> 4:265-270.  |      |                               |                 |                          |                               |
|  | AP | Linsley, P.S. <i>et al.</i> (1993) "The Role of the CD28 Receptor During T Cell Responses to Antigen" <i>Annu. Rev. Immunol.</i> 11:191-212.   |      |                               |                 |                          |                               |
|  | AQ | Boon, T. <i>et al.</i> (1994) "Tumor Antigens Recognized by T Lymphocytes" <i>Annu. Rev. Immunol.</i> 12:337-365.  |      |                               |                 |                          |                               |
|  | AR | Garido, F. <i>et al.</i> (1993) "Natural History of HLA Expression During Tumour Development" <i>Immunology Today</i> 14(10):491-499.  |      |                               |                 |                          |                               |
|  | AS | Gerlach, J.H. <i>et al.</i> (1986) "Multidrug Resistance" <i>Cancer Surveys</i> 5(1):25-46.  |      |                               |                 |                          |                               |
|  | AT | Allison, J.P. (1994) "CD28-B7 Interactions in T-Cell Activation" <i>Current Opinion in Immunology</i> 6:414-419.   |      |                               |                 |                          |                               |
|  | AU | Schwartz, R.H. (1992) "Costimulation of T Lymphocytes: The Role of CD28, CTLA-4, and B7/BB1 in Interleukin-2 Production and Immunotherapy" <i>Cell</i> 71:1065-1068.   |      |                               |                 |                          |                               |
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|  | AL |                 |      |         |       |          |                       |

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|  |    |  |
|--|----|--|
|  | AM | Cromme, F.V. <i>et al.</i> (1994) "Loss of Transporter Protein, Encoded by the TAP-1 Gene, Is Highly Correlated With Loss of HLA Expression in Cervical Carcinomas" <i>J. Exp. Med.</i> 179:335-340.   |
|  | AN | Frei, U. <i>et al.</i> (1993) "Malignancies Under Cyclosporine After Kidney Transplantation: Analysis of a 10-Year Period" <i>Transplantation Proceedings</i> 25(1):1394-1396.                         |
|  | AO | Calabresi, P. and Chabner B.A. <i>In</i> : Goodman and Gilman, The Pharmacological Basis of Therapeutics (Pergamon Press, 8 <sup>th</sup> Edition) pp. 1209-1216.                                      |
|  | AP | Restifo, N.P. <i>et al.</i> (1993) "Identification of Human Cancers Deficient in Antigen Processing" <i>J. Exp. Med.</i> 177:265-272.  |
|  | AQ | Houghton, A.N. (1994) "Cancer Antigens: Immune Recognition of Self and Altered Self" <i>J. Exp. Med.</i> 180:1-4.  |
|  | AR | Chong, H. <i>et al.</i> (1996) "Expression of Co-Stimulatory Molecules by Tumor Cells Decreases Tumorigenicity but May Also Reduce Systemic Antitumor Immunity" <i>Human Gene Therapy</i> 7:1771-1779. |
|  | AS | Alegre <i>et al.</i> (1994) "Severe Combined Immunodeficient Mice Engrafted with Human Splenocytes Have Functional Human T Cells and Reject Human Allografts" <i>J. Immunol.</i> 153:2738-2749.        |
|  | AT | McBride <i>et al.</i> (1995) "Human Immunodeficiency Virus Infection of Xenografted SCID-beige Mice" <i>J. Med. Virology</i> 47:130-138.   |
|  | AU |  |

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